

Serial No.: 10/722,574
Atty. Docket No.: P66852US3

REMARKS

The Final Office Action mailed December 26, 2007, has been carefully reviewed and, by this Amendment, claims 1, 13-15 and 17-19 have been amended. Claims 1-20 are pending. Claims 1 and 19 are independent. Claims 2-5 and 7-11 are withdrawn.

As an initial matter, Applicants have amended the specification to correspond with textual changes made in the claims. No new matter has been added.

The Examiner rejected claims 1, 12, 13 and 18-20 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,750,875 to Juster. The Examiner also rejected claims 1, 6, 13, 14 and 16-19 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,335,723 to Waldman, Jr. ("Waldman").

As clarified in amended claims 1 and 19, the present invention is directed to a kit for preparing a urinary catheter for draining a human bladder. The kit includes a first proximal catheter section and a second distal catheter section which are arranged in a coextending fashion and define a longitudinally extending passage therein. When the kit is configured for storage, a tubular protective member surrounds/covers the first catheter section, but the second catheter section is not covered and hence is exposed to the ambient environment in the storage configuration

Serial No.: 10/722,574
Atty. Docket No.: P66852US3

(see Figures 12 and 13; and page 13, lines 20-21). This is not disclosed or suggested in Juster.

Furthermore, claims 1 and 19 have been amended to further define the tubular member as having an open end that is removably connected to the second catheter section and a *closed end that is distal from the open end*. When the open end of the tubular member is sealingly connected to the second catheter section, i.e., in the storage configuration, the fact that the other end of the tubular member is closed results in the annular cavity between the first catheter section and the inner diameter of the tubular member being a closed cavity so as to prevent any friction-reducing or hydrophilic swelling medium contained therein from escaping through either end. As a result, the first catheter section can be stored in a ready-to-use condition while being enclosed only by the tubular member which must be completely removed before the first catheter section can be inserted into the urethra. This is not shown or suggested by Juster or Waldman.

Juster discloses a packaged catheter arrangement in which a pliable latex rubber catheter is supported within a tube sheath, both of which are enclosed as a unit within a sealed overpackage for storage. The tube sheath prevents the pliable catheter from sliding down in the overpackage and becoming kinked (see column 1,

Serial No.: 10/722,574
Atty. Docket No.: P66852US3

lines 20-30), while the overpackage provides a sealed enclosure to retain the entire catheter in a sterile condition prior to use (see column 1, lines 42-49; column 2, lines 55-65). Both ends of the tubular sheath are open. Since the overpackage provides the sealed protection to the catheter, and the tube sheath is intended only to provide structural rigidity to the catheter, there is nothing in Juster that would suggest closing one end of the sheath in the manner claimed by the present invention as this would serve no purpose in Juster.

Further, all of the catheter of Juster is fully enclosed by the overpackage when in the storage configuration, including the distal catheter section 15. This complete coverage is mandatory in Juster since the tubular sheath does not provide a closed cavity around even the proximal catheter section and most certainly does not sealingly enclose the distal section. Nor is there anything in Juster to suggest how the distal catheter section could possibly be modified so as to be exposed to the ambient environment during storage, while retaining sterility. For at least the foregoing reasons, claims 1 and 19 are clearly patentable over Juster.

Waldman is directed to an indwelling catheter intended for intravenous administration of fluids and is *not suitable for draining a human bladder* as claimed by the present invention.

Serial No.: 10/722,574
Atty. Docket No.: P66852US3

Rather, Waldman includes a needle 11 for insertion into a vein. The needle is attached to a take-up tube 14 which is coupled to a catheter 17 that is protected by a sleeve 20. The ends of the sleeve 20 are attached to the needle hub 12 at one end and a connector hub 18 at the other end by rubber bands, plastic tape, etc. (see column 1, line 67 to column 2, line 21). In use, the sleeve is gathered onto the take-up tube 14 in an accordion fashion as the catheter is inserted into the vein (see Figures 2 and 3; column 2, lines 51-62).

First, Waldman does not disclose or suggest a tubular member that, when connected to the catheter, defines an annular cavity between the tubular member and the catheter that is closed at both ends so as to accommodate a friction-reducing substance therein and prevent the escape of such substance through either end, as claimed by the present invention. The rubber-banded connections of the sleeve to the hubs are not disclosed as being tight enough to contain and prevent the escape of a friction-reducing substance placed within the sleeve and, more significantly, there is nothing to suggest any use for or benefit to having a friction-reducing substance in the space between the sleeve and the catheter 17. On the contrary, having such a substance within this space would only hinder the intended function

Serial No.: 10/722,574
Atty. Docket No.: P66852US3

by which the sleeve is gathered in an accordian fashion as the catheter is inserted.

Second, the sleeve in Waldman is clearly intended to remain in place, covering the catheter, throughout use of the catheter unit; *it does not have to be, nor is it supposed to be, removed* in order to render the catheter ready for insertion. And even when the catheter of Waldman is ready for insertion, it is not suitable for insertion *into the urethra*.

For at least the foregoing reasons, claims 1 and 19 are patentable over the prior art. Claims 2-18 and 20 are also in condition for allowance as claims properly dependent on an allowable base claim. Entry of the foregoing amendments and allowance of the application is requested.

The Examiner also provisionally rejected claims 1, 6 and 12-20 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-26 and 54-65 of copending Application No. 10/184,081 or claims 1-21 of copending Application No. 10/537,014. Because the conflicting claims have not been patented, the rejection is provisional only. Accordingly, Applicants request deferral of the requirement for further response in connection with this obviousness-type double patenting issue

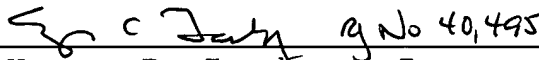
Serial No.: 10/722,574
Atty. Docket No.: P66852US3

until patentable subject matter has in fact been identified in at least one of the subject applications.

With the foregoing amendments and remarks, the application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By  No 40,495
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
Telephone: (202) 638-6666
Date: June 25, 2008
HBJ:SCB
R:\SBAILEY\2008\06-08\P66852U3 - Amd.wpd